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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,000	07/02/2001	Bret A. Ferree	BAF-11302/29	1159

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EXAMINER
WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
1647	8

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,000	FERREE, BRET A.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *5 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's election of Species: *BMP-1* as pertaining to the instant Invention in Paper No. 7 (13 February 2003) is acknowledged. It should be noted that claims will be examined insofar as they read on the elected Invention. Claims 5 and 6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-4 and 7 are under examination in the Instant Application.

Claim Objections/Rejections

Claim Objections.

Claim 4 is objected to because it recites or encompasses non-elected inventions.

Appropriate correction is required.

Claim Rejections- 35 USC § 112, first paragraph - lack of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the subject matter was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for the limitations of the claims wherein a growth factor or differentiation factor is injected into the spinal canal or disc to treat disc herniation or degenerative disc disease.

Claims 1-4 and 7 read on a method of treating disc herniation or degenerative disc disease by injecting a growth factor, BMP-1, directly into the disc or into the spinal canal. Dependent claims recite use of growth factors extracted from a patient's blood or made recombinantly.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification discusses spinal anatomy (p. 1-2), disc anatomy (p. 4), and the treatments available (mostly surgical) to correct herniated or degenerating spinal discs (p. 4-5). The specification also describes a method for extracting growth factors from human blood (p. 6, 78).

However, the claims read on a method of treating disc herniation or degenerative disc disease by injecting a growth factor, such as BMP-1, directly into a vertebral disc or into or near the spinal cord. There is no enabling discussion or working examples disclosed in the instant application as to how to practice the claimed method of treating disc herniation or degenerative disc disease by injecting BMP-1 into the disc or in the region of the disc. This lack of enabling data in the instant Specification is particularly important since BMP-1 is a poorly-characterized growth factor related to peptides that control a *wide variety* of cell determination, growth and differentiation processes (Padgett, et al, 1993, PNAS, 90: 2905-2909). Presumably, the claimed invention seeks to cause growth of connective tissue within the paravertebral disc itself. Yet it is not known if BMP-1 can cause chondrocyte proliferation at all. Neither is it known how well the extent and location of cell proliferation can be controlled by adding BMP-1 into or near the disc. Similar studies performed in dogs with a related peptide caused *bone* growth (Paramore, et al, 1999, Neurosurgery, 44(5): 1151-1155). The authors of that study injected OP-1 into the subarachnoid space above lumbar spinal segments. They obtained new calcified growths at the sites of injection of OP-1; however, they could not fine-tune the resultant size and shape of the bony structures. Paramore, et al caution that, in fact, spinal cord *compression* can be the result of subarachnoid OP-1 injection (p. 1154). In addition, BMP-1 is related to a family of growth factors that cause many effects, including cell differentiation and proliferation. It is not known, nor is it predictable, what the precise cellular function of BMP-1 is. It is known that BMP-4 is involved in body segmentation during development, not in chondrocyte proliferation or differentiation (Padgett, et al 1993, PNAS, 90: 2905-2909). These references and others

demonstrate that there is no reason one can infer a specific cellular function for BMP-1, such that the growth factor can be used to treat intervertebral disc herniation or degeneration.

Furthermore, the Specification is not enabling for use of other growth factors, as recited in Claim 4, for the reasons given above for BMP-1: the family of growth factors has wide-ranging effects, therefore it is not predictable what the effects are for a new or unidentified growth factor.

Due to the large quantity of experimentation required to determine: how to use the disclosed BMP-1 growth factor to treat disc herniation or degenerative disc disease; the lack of direction or guidance in the specification regarding the same; the lack of working examples that apply BMP-1 into or near an intervertebral disc in a mammal or vertebrate; the state of the art showing the complexities of causing tissue growth *in situ*; and the breadth of the claims which embrace many types of growth factors, --undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, second paragraph-indefiniteness.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1, 2, 3 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 7 recite the phrase "spinal canal." It is not known if the "spinal canal" referred to in the claims is the *central canal*, a small canal found in the center of the spinal cord (that carries cerebral-spinal fluid), or to the relatively large space above the spinal cord and dura into which spinal injections are usually given.

Claims 2 and 3 are rendered indefinite because they fail to recite positive method steps involved in "concentrating and releasing the growth or differentiation factors from a patient's blood" and in "obtaining the growth or differentiation factors from recombinant genetic techniques or animal sources."

Conclusion

No claims are allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The

examiner can normally be reached Monday - Friday from 8:30 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW
4/14/03

Gary L. Kunz
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